that may issue based on this proposal become effective 30 days after its publication in the **Federal Register**.

XIV. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday,

1. Petition for the reclassification of hip joint metal/polymer constrained cemented or uncemented prosthesis submitted by the Orthopedic Surgical Manufacturers Association, Warsaw, IN, dated June 1, 1999, amended June 8 and August 27, 1999.

2. Transcript of the Orthopedic and Rehabilitation Devices Panel Meeting, November 4, 1999, pp. 25 to 142.

List of Subjects in 21 CFR Part 888

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 888 be amended as follows:

PART 888—ORTHOPEDIC DEVICES

1. The authority citation for 21 CFR part 888 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 888.3310 is revised to read as follows:

§ 888.3310 Hip joint metal/polymer constrained cemented or uncemented prosthesis.

(a) *Identification.* A hip joint metal/polymer constrained cemented or uncemented prosthesis is a device intended to be implanted to replace a hip joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and an acetabular component made of ultra-high-molecular-weight polyethylene with or without a metal shell, made of alloys, such as cobalt-chromium-molybdenum and titanium alloys. This generic type of device is intended for use with or without bone cement (§ 888.3027).

(b) *Classification.* Class II (special controls). This special control for this device is the FDA guidance document entitled ''Class II Special Controls Guidance Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis.''

Dated: August 22, 2001.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 01–22286 Filed 9–5–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1301, 1304, 1305 and 1306

[DEA–208P]

RIN 1117–AA58

Allowing Central Fill Pharmacies To Fill Prescriptions for Controlled Substances on Behalf of Retail Pharmacies

AGENCY: Drug Enforcement Administration (DEA), Justice

ACTION: Notice of proposed rulemaking

SUMMARY: DEA is proposing to amend its regulations to provide for the use of central fill pharmacies, also known as refill pharmacies, fulfillment centers, or call centers. Unlike retail pharmacies which dispense controlled substances directly to the patient, central fill pharmacies provide a service to retail pharmacies by preparing and packaging prescriptions for retail pharmacies to dispense to the patient. Prescription information is transmitted from a retail pharmacy to a central fill pharmacy where the prescription is filled or refilled. The filled prescription is delivered to the retail pharmacy for pick up by the patient. Industry has expressed interest in utilizing central fill pharmacy operations to allow for more efficient delivery of prescriptions to patients. With this rulemaking, DEA is proposing to expand the definition of ''dispense'' to include the activities of central fill pharmacies. Mail order and Internet pharmacies, which currently obtain prescriptions from and dispense directly to a patient, are not affected by this regulation. They will continue to be registered as retail pharmacies.

DATES: Written comments must be submitted on or before November 5, 2001.

ADDRESSES: Comments should be submitted in triplicate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA **Federal Register** Representative/CCR.

FOR FURTHER INFORMATION CONTACT: Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537. Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

What Is the Purpose of the Proposed Rule?

DEA is proposing these amendments in response to significant changes taking place in the pharmacy industry. Increased demands are being placed on traditional pharmacy systems by the rapid growth in the number of prescriptions written and dispensed. The National Association of Chain Drugstores recently estimated that in 2005, pharmacists in the United States will fill over 4 billion prescriptions. While the number of prescriptions dispensed is growing dramatically, the United States is facing a severe pharmacist shortage. Between 1999–2004, the volume of prescriptions dispensed in retail pharmacies is expected to increase 35%, while during the same period the number of available pharmacists is projected to increase only 6%. These factors have forced the pharmacy industry to seek new ways to increase efficiency while maintaining quality patient care. By transferring some of the time-consuming, non-clinical duties such as prescription filling to central fill pharmacies, traditional retail pharmacies can dedicate more time to assisting patients.

In response to industry's interest in improving efficiency by implementing the concept of central fill pharmacies, DEA contacted a variety of relevant trade associations and professional organizations to obtain more information on the issue. Several segments of the industry submitted written comments to DEA's solicitation; two others, including one trade association and one company, requested to meet with DEA to provide additional information. After considering the issues raised by industry, DEA determined that changes to the regulations would be appropriate and would give industry needed flexibility to accommodate the tremendous growth in the number of prescriptions presented for dispensing.

DEA's current regulations do not permit the utilization of central fill pharmacies for the dispensing of controlled substances. With this rulemaking, DEA is proposing several amendments to its regulations to allow for the use of central fill pharmacies, subject to certain restrictions, in states where such activities are permitted. While DEA is committed to responding to emerging industry practices, such as central fill pharmacies, which will

allow for more efficient delivery of prescription drugs, its primary responsibility is to prevent the diversion of controlled substances. Therefore, some restrictions on the use of central fill pharmacies are necessary.

What Do the Regulations Currently Permit?

At present, there is no provision in DEA's regulations for central fill pharmacy operations. Retail pharmacies, including those which utilize the mail service and the Internet, are registered by DEA to dispense prescriptions for controlled substances directly to the patient. ''Dispensing'' is defined in the Controlled Substances Act as delivering a controlled substance ''to an ultimate user'' (21 U.S.C. 802(10)). DEA regulations do not currently provide for central fill pharmacy operations which fill prescriptions for delivery to a traditional retail pharmacy. Allowing central fill pharmacies to fill prescriptions on behalf of retail pharmacies for subsequent dispensing to the ultimate user is a legitimate extension of current practice.

What Would the Proposed Regulations Allow?

This notice proposes to allow central fill pharmacies to become registered as practitioners under 21 CFR 1301.13(e)(1)(iii) so long as and to the extent that their activities are authorized by the state in which they are located. At present, the business activities under 21 CFR 1301.13(e)(1)(iii) include practitioners, hospitals/clinics, retail pharmacies, and teaching institutions. DEA is proposing to create a new business activity to be known as ''central fill pharmacies.'' This would allow the central fill pharmacy to prepare prescriptions for controlled substances in Schedules II-V for dispensing to a patient by a registered traditional retail pharmacy pursuant to a prescription issued by an authorized practitioner and communicated to the central fill pharmacy by the retail pharmacy.

DEA has determined that central fill pharmacy activities are better characterized as ''dispensing'' activities as opposed to ''distributing'' activities. Therefore, central fill pharmacies will not be limited by the restrictions on ''distributions'' from one practitioner to another set forth in 21 CFR 1307.11, in particular the 5% limitation which limits the amount of controlled substances that can be distributed by one practitioner to another. Similarly, no official order forms (DEA Form 222) will be required for transfer of Schedule II controlled substances from a central fill pharmacy to a retail pharmacy since DEA considers this activity to be a form of dispensing, not distribution. 21 CFR 1305.03 is proposed to be amended to clarify that the order form requirement does not apply to such transfers.

Central fill pharmacies would be permitted to prepare both initial and refill prescriptions, subject to all applicable state and federal regulations. Only a licensed pharmacist may fill such prescriptions (21 CFR 1306.06). By definition, the filled prescriptions must be transported to a retail pharmacy for delivery to the patient. Both the pharmacist employed by the central fill pharmacy and the pharmacist who dispenses the prescription to the patient will be responsible for insuring that the prescription was issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice and otherwise in the manner specified by DEA regulations (21 CFR 1306.04(a), 1306.05(a)).

This notice proposes to allow a central fill pharmacy to prepare prescriptions on behalf of retail pharmacies with which it has a contractual agreement to provide such services or with which it shares a common owner. The central fill pharmacy would be required to keep a list of retail pharmacies for which it has agreed to provide such services. The central fill pharmacy would also be required to keep current copies of the Certificates of Registration for each retail pharmacy for which it is authorized to fill prescriptions. Similarly, retail pharmacies would be required to keep a list of those central fill pharmacies, along with current copies of their DEA Certificates of Registration, permitted to prepare prescriptions on their behalf. This information must be made available for inspection upon request by DEA.

A central fill pharmacy will not be permitted to prepare prescriptions provided directly by a patient or individual practitioner or to mail or otherwise deliver a filled prescription directly to a patient or individual practitioner. If a retail pharmacy and a central fill pharmacy are operated from the same location, each must be separately registered with DEA and maintain separate stock, inventories, and records.

Retail pharmacies would be permitted to transmit prescription information to a central fill pharmacy in two ways. First, a facsimile of a prescription for a controlled substance in Schedule II, III, IV or V may be provided by the retail pharmacy to the central fill pharmacy. The retail pharmacy must maintain the original hard copy of the prescription and the central fill pharmacy must maintain the facsimile of the prescription. Alternatively, DEA is proposing to allow the prescription information to be communicated electronically by the retail pharmacy to the central fill pharmacy. Since there appears to be little risk that an outside party will divert such prescription information, DEA is not proposing specific security standards with respect to electronic transmission in this particular situation. DEA will soon propose standards for electronic transmission of prescription information in a separate rulemaking. When setting up the transmission system, the participating pharmacies must be mindful of all federal and state requirements regarding patient confidentiality, network security, and use of shared databases. Both pharmacies must maintain the prescription information in a readily retrievable manner and comply with all applicable federal and state recordkeeping requirements.

With respect to security, central fill pharmacies would be required to comply with the same security requirements applicable to other practitioners (21 CFR 1301.71, 1301.75, 1301.76). While not specifically required by DEA regulations, central fill pharmacies may choose to implement additional security measures based on the volume of controlled substances handled, number of employees in the facility, or other unique factors. Such additional security measures may be needed in order to comply with the general requirement to maintain effective controls and procedures to guard against theft and diversion of controlled substances (21 CFR 1301.71). As indicated above, since pharmacists at central fill pharmacies will be preparing prescriptions for controlled substances, they shall bear a corresponding responsibility, along with the pharmacist at the retail pharmacy, for the proper dispensing of the prescription (21 CFR 1306.04(a), 1306.05(a)). Additionally, central fill pharmacies must be vigilant in their choice of carriers to transport filled prescriptions to retail pharmacies and be aware of their responsibilities for reporting in-transit losses (21 CFR 1301.74(e)).

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Assistant Administrator, Office of Diversion Control, hereby certifies that this rulemaking has been

drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation, and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities. In fact, it is anticipated that this rule, by affording additional flexibility to pharmacies in the dispensing of prescriptions, will help lower total health care costs.

Executive Order 12866

The Deputy Assistant Administrator, Office of Diversion Control, further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 Section 1(b). DEA has determined that this is not a significant rulemaking action. Therefore, this action has not been reviewed by the Office of Management and Budget.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988.

Executive Order 13132

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100,000,000 or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Plain Language Instructions

The Drug Enforcement Administration makes every effort to write clearly. If you have suggestions as to how to improve the clarity of these regulations, call or write Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537. Telephone (202) 307–7297.

List of Subjects

21 CFR Part 1300

Definitions, Drug traffic control

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures

21 CFR Part 1304

Drug traffic control, Reporting requirements

21 CFR Part 1305

Drug traffic control, Reporting requirements

21 CFR Part 1306

Drug traffic control, prescription drugs

For the reasons set out above, Title 21, Code of Federal Regulations, Parts 1300, 1301, 1304, 1305, and 1306 are proposed to be amended to read as follows:

PART 1300—[AMENDED]

1. The authority citation for part 1300 continues to read as follows:

Authority: 21 U.S.C. 802, 871(b), 951, 958(f).

2. Section 1300.01 is proposed to be amended by redesignating the existing paragraphs (b)(6) through (42) as (b)(7) through (43) and by adding a new paragraph (b)(6) to read as follows:

§ 1300.01 Definitions relating to controlled substances.

* * * * *

(b) * * *

(6) The term central fill pharmacy means a pharmacy which is authorized by the state in which it is located to prepare controlled substances orders for dispensing pursuant to a valid prescription transmitted to it by a registered retail pharmacy and to return the labeled and filled prescriptions to the retail pharmacy for delivery to the ultimate user. A pharmacist employed by a central fill pharmacy may only fill controlled substance prescriptions pursuant to a written or electronic prescription provided by a retail pharmacy.

* * * * *

PART 1301—[AMENDED]

1. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 871(b), 875, 877.

2. Section 1301.13(e)(1)(iii) is proposed to be revised to read as follows:

§ 1301.13 Application for registration; time for application, expiration date, registration for independent activities; application forms, fees, contents and signature; coincident activities.

* * * * *

(e) * * *

(1) * * *

(iii) Dispensing or Instructing (Includes Practitioner, Hospital/Clinic, Retail Pharmacy, Central Fill Pharmacy, Teaching Institution).	Schedules II–V	New—224 ..... Renewal—224a	210 210	3	May conduct research and instructional activities with those substances for which registration was granted, except that a mid-level practitioner may conduct such research only to the extent expressly authorized under state statute. A pharmacist may manufacture an aqueous or oleaginous solution or solid dosage form containing a narcotic controlled substance in Schedule II–V in a proportion not exceeding 20% of the complete solution, compound or mixture.

* * * * *

3. Section 1301.76 is proposed to be amended by adding new paragraph (d) to read as follows:

§ 1301.76 Other security measures for practitioners.

* * * * *

(d) Central fill pharmacies must comply with § 1301.74(e) when selecting private, common or contract carriers to transport filled prescriptions to a retail pharmacy for delivery to the ultimate user. When central fill pharmacies contract with private, common or contract carriers to transport filled prescriptions to a retail pharmacy, the central fill pharmacy is responsible for reporting in-transit losses upon discovery of such loss by use of a DEA Form 106. Retail pharmacies must comply with § 1301.74(e) when selecting private, common or contract carriers to retrieve filled prescriptions from a central fill pharmacy. When retail pharmacies contract with private, common or contract carriers to retrieve filled prescriptions from a central fill pharmacy, the retail pharmacy is responsible for reporting in-transit losses upon discovery of such loss by use of a DEA Form 106.

PART 1304—[AMENDED]

1. The authority citation for Part 1304 continues to read as follows:

Authority: 21 U.S.C. 821, 827, 871(b), 958(e), 965, unless otherwise noted.

2. Section 1304.04 is proposed to be amended by adding the new paragraph (i) to read as follows:

§ 1304.04 Maintenance of records and inventories.

* * * * *

(i) If a central fill and retail pharmacy are located at the same premises, each must maintain separate inventories of controlled substances, as well as separate records.

3. New § 1304.05 is proposed to be added to read as follows:

§ 1304.05 Records of authorized central fill pharmacies and retail pharmacies.

(a) Every retail pharmacy that utilizes the services of a central fill pharmacy must keep a record of all central fill pharmacies, including name, address and DEA number, that are authorized to fill prescriptions on its behalf. The retail pharmacy must also maintain a current copy of the Certificate of Registration for each central fill pharmacy authorized to fill prescriptions on its behalf. These records must be made available upon request for inspection by DEA investigators.

(b) Every central fill pharmacy must keep a record of all retail pharmacies, including name, address and DEA number, for which it is authorized to fill prescriptions. The central fill pharmacy must also maintain a current copy of the Certificate of Registration for all retail pharmacies for which it is authorized to fill prescriptions. These records must be made available upon request for inspection by DEA investigators.

PART 1305—[AMENDED]

1. The authority citation for part 1305 continues to read as follows:

Authority: 21 U.S.C. 821, 828, 871(b), unless otherwise noted.

2. Section 1305.03 is proposed to be revised to read as follows:

§ 1305.03 Distributions requiring order forms.

An order form (DEA Form 222) is required for each distribution of a Schedule I or II controlled substance except to persons exempted from registration under part 1301 of this chapter; which are exported from the United States in conformity with the Act; for delivery to a registered analytical laboratory, or its agent approved by DEA; or for transfer from a central fill pharmacy as defined in 21 CFR 1300.01(b)(6) to a retail pharmacy.

PART 1306—[AMENDED]

1. The authority citation for Part 1306 continues to read as follows:

Authority: 21 U.S.C. 821, 829, 871(b), unless otherwise noted.

2. Section 1306.05(a) is proposed to be revised to read as follows:

§ 1306.05 Manner of issuance of prescriptions.

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner. A practitioner may sign a prescription in the same manner as he would sign a check or legal document (e.g., J.H. Smith or John H. Smith). Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescriptions may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist, including a pharmacist employed by a central fill pharmacy, who fills a prescription not prepared in the form prescribed by these regulations.

* * * * *

3. Section 1306.06 is proposed to be revised to read as follows:

§ 1306.06 Persons entitled to fill prescriptions.

A prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy, a registered central fill pharmacy, or registered institutional practitioner.

4. Section 1306.11 is proposed to be amended by adding a new paragraph (d)(5)to read as follows:

§ 1306.11 Requirement of prescription.

* * * * *

(d) * * *

(5) Central fill pharmacies shall not be authorized under this paragraph to prepare prescriptions for a controlled substance listed in Schedule II upon receiving an oral authorization from a retail pharmacist or an individual practitioner.

* * * * *

5. Section 1306.14 is proposed to be amended by redesignating existing paragraphs (b) and (c) as paragraphs (c) and (d), and by adding a new paragraph (b) to read as follows:

§ 1306.14 Labeling of substances and filling of prescriptions.

* * * * *

(b) If the prescription is filled at a central fill pharmacy, the central fill pharmacy shall affix to the package a label showing the retail pharmacy name and address and a unique identifier, (i.e. the central fill pharmacy's DEA registration number) indicating that the prescription was filled at the central fill pharmacy, in addition to the information required under paragraph (a) of this section.

* * * * *

6. A new § 1306.15 is proposed to be added to read as follows:

§ 1306.15 Transfer of prescription information between retail pharmacies and central fill pharmacies for prescriptions of Schedule II controlled substances.

Prescription information may be transferred between a retail pharmacy and a central fill pharmacy for dispensing purposes only if permitted under state law and only if the retail pharmacy and central fill pharmacy

have a contractual relationship providing for such activities or share a common owner. The following requirements shall also apply:

(a) Prescriptions for controlled substances listed in Schedule II may be transmitted from a retail pharmacy to a central fill pharmacy via facsimile or a common, real-time electronic database. The retail pharmacy transmitting the prescription information must:

(1) Write the word ''CENTRAL FILL'' on the face of the original transmitted prescription, if sent via facsimile;

(2) Record and transmit to the central fill pharmacy (on the reverse side of the transmitted prescription, if sent via facsimile) the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted and the retail pharmacy from which transmitted, the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal;

(3) Ensure that all information required to be on a prescription pursuant to § 1306.05 of this part is transmitted to the central fill pharmacy (either on the face of the prescription or in the electronic transmission of information);

(4) Maintain the original prescription for a period of two years from the date the prescription was filled;

(5) Keep a record of receipt of the filled prescription, including the method of delivery (private, common or contract carrier) and the name of the retail pharmacy employee accepting delivery.

(b) The central fill pharmacy receiving the transmitted prescription must:

(1) Keep a copy of the prescription (if sent via facsimile) or an electronic record of all the information transmitted by the retail pharmacy, including the name, address, and DEA registration number of the retail pharmacy transmitting the prescription;

(2) Keep a record of the date of receipt of the transmitted prescription, the name of the licensed pharmacist filling the prescription, and the date of filling of the prescription;

(3) Keep a record of the date the filled prescription was delivered to the retail pharmacy and the method of delivery (i.e. private, common or contract carrier).

7. Section 1306.24 is proposed to be amended by redesignating the existing paragraphs (b) and (c) as paragraphs (c) and (d), and by adding a new paragraph (b) to read as follows:

§ 1306.24 Labeling of substances and filling of prescriptions.

* * * * *

(b) If the prescription is filled at a central fill pharmacy, the central fill pharmacy shall affix to the package a label showing the retail pharmacy name and address and a unique identifier, (i.e. the central fill pharmacy's DEA registration number) indicating that the prescription was filled at the central fill pharmacy, in addition to the information required under paragraph (a) of this section.

* * * * *

8. Section 1306.26 is proposed to be amended by adding a new paragraph (g) to read as follows:

§ 1306.26 Dispensing without prescription.

* * * * *

(g) Central fill pharmacies shall not be permitted to dispense controlled substances to a purchaser at retail pursuant to this section.

9. A new § 1306.27 is proposed to be added to read as follows:

§ 1306.27 Transfer of prescription information between retail pharmacies and central fill pharmacies for initial and refill prescriptions of Schedule III, IV, or V controlled substances.

Prescription information may be transferred between a retail pharmacy and a central fill pharmacy for dispensing purposes only if permitted under state law and only if the retail pharmacy and central fill pharmacy have a contractual relationship providing for such activities or share a common owner. The following requirements shall also apply:

(a) Prescriptions for controlled substances listed in Schedule III, IV or V may be transmitted from a retail pharmacy to a central fill pharmacy via facsimile or a common, real-time electronic database. The retail pharmacy transmitting the prescription information must:

(1) Write the word ''CENTRAL FILL'' on the face of the original transmitted prescription, if sent via facsimile;

(2) Record and transmit to the central fill pharmacy (on the reverse side of the transmitted prescription, if sent via facsimile) the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted and the retail pharmacy from which transmitted, the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal;

(3) Ensure that all information required to be on a prescription pursuant to Section 1306.05 of this part is transmitted to the central fill pharmacy (either on the face of the prescription or in the electronic transmission of information);

(4) Indicate in the information transmitted the number of refills already dispensed and the number of refills remaining;

(5) Maintain the original prescription for a period of two years from the date the prescription was last refilled;

(6) Keep a record of receipt of the filled prescription, including the method of delivery (private, common or contract carrier) and the name of the retail pharmacy employee accepting delivery.

(b) The central fill pharmacy receiving the transmitted prescription must:

(1) Keep a copy of the prescription (if sent via facsimile) or an electronic record of all the information transmitted by the retail pharmacy, including the name, address, and DEA registration number of the retail pharmacy transmitting the prescription;

(2) Keep a record of the date of receipt of the transmitted prescription, the name of the licensed pharmacist filling the prescription, and dates of filling or refilling of the prescription;

(3) Keep a record of the date the filled prescription was delivered to the retail pharmacy and the method of delivery (i.e. private, common or contract carrier).

Dated: August 27, 2001.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 01–22322 Filed 9–5–01; 8:45 am]

BILLING CODE 4410–09–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[PA041–4153; FRL–7049–7]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Reasonably Available Control Technology Requirements for Volatile Organic Compounds and Nitrogen Oxides in the Philadelphia-Wilmington-Trenton Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to remove the limited status of its approval of the Commonwealth of Pennsylvania State Implementation Plan (SIP) revision that requires all major sources of volatile organic compounds (VOC) and nitrogen oxides (NO_X) to implement reasonably available control technology (RACT) as it applies in the Philadelphia-Wilmington-Trenton ozone nonattainment area (the Philadelphia